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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	U022 1020.1	1163

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,657	WOOLEY ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-15,18-22 and 56-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-15,18-22,56-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Amendment/Response dated 5/16/06.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1,2,5,7,8,12-15,18-22, and 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484) and Cuny et al (USPN 6,207,679 hereafter '679). The claims are drawn to a method of inhibiting the proliferation of a bacterial infection in a skin or mucosal injury by applying a formulation comprising an antibacterial agent and a chelating agent working synergistically.

4. The '484 patent teaches a methods of treating bacterial and fungal infections topically by applying a composition comprising antibacterial/fungal agents working synergistically with chelating agents such as EDTA and active agents such as amphotericin (col. 8, lin. 19-30; col. 14, lin. 25-33 and 58-67). The dosage forms though preferably intravenous, include topical, oral, nasal, buccal, rectal, and vaginal (col. 16, lin. 25-32). The dosage forms include carriers, solvents and an aqueous medium, as well as common oral excipients like mannitol, lactose and starch (col. 15, lin. 50-col. 17, lin. 36). The fungal infections treated by the invention are assessed by one of ordinary skill and treated according to the patients' body weight, resistance to

medication and other factors that would be routine to one of ordinary skill in the art to ascertain. The reference though using traditional antibacterial compounds to treat fungal infections is silent to the treatment of bacterial infections.

5. The '679 patent teaches the use of antimicrobial agents in the treatment of infections (bacterial/fungal) in wounds such as burns, ulcers, scrapes and bruises (abstract, col. 34, lin. 40-55). The formulations can be used to sterilize medical devices or treat bacterial or fungal infections on internal mucosa, both orally and vaginally (*Ibid.*). Formulations include solutions, elixirs and mouthwashes (col. 38, lin. 46-57). The formulation is effective against both Gram-positive and negative bacterial genus such as *Pseudomonas* and *Staphylococcus* (col. 32, lin. 17-39). The formulation comprises various antimicrobial agents such as penicillins, amino glycosides, and cephalosporins along with carriers and chelators such as EDTA (col. 36, lin. 7-16; col. 38, lin. 19-20). A skilled artisan would have been motivated by these teachings to administer the formulation of '484 to the skin for wound treatment as taught by '679.

6. With these things in mind one of ordinary skill in the art would have been motivated to follow the teachings of '679 to combine biocidal compounds such as those found in both '679 and '484 in order to treat Gram-positive or negative bacterial infections. The '484 teaches the importance of a synergistic relationship between the chelator and the biocide, while the '679 teaches the varying methods of application. The minimum inhibitory concentration (MIC) for each compound would be known by one of ordinary skill in the art as shown in the '679 patent. It would have been obvious to follow the suggestions of '679 and '484 in order to topically treat bacterial infections with an expected result of a method of treating infected wounds.

7. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484), Cuny et al (USPN 6,207,679 hereafter '679) and Raad et al (USPN 5,688,516 hereafter '516). The claims are drawn to a method of treating a bacterial infection with a composition comprising biocidal agents and chelators.

8. As discussed above the combination of the '484 and '679 teach methods of treating various skin injuries and with biocidal formulations. The teachings are however silent to the inclusion of the particular tetracycline claimed by applicant or the specific chelator although the substitution of these compounds would be well within the limits of one of ordinary skill in the art, as shown in the '516 patent.

9. The '516 patent discloses a method of treating Gram positive and negative bacterial infections by applying a composition of chelating agents such as EDTA and triethylene tetramine dihydrochloride and various anti-bacterial agents including oxytetracycline (col. 4, lin. 31 – 53; col. 5, lin. 37-53). One of ordinary skill in the art would have been motivated to include the chelators or tetracycline of the '516 patent in order to treat a wider range of infections.

10. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '516 patent into the combination of '679 and '484 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with en expected result of a topical wound healing formulation capable of treating a wider range of infections.

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Raad et al (USPN 6,165,484 hereafter '484), Cuny et al (USPN 6,207,679 hereafter '679) and Kruse et al (USPN 5,646,151 hereafter '151). The claims are drawn to a method of treating a bacterial infection with a topical biocidal formulation comprising specific antibacterial agents.

12. As discussed above the combination of the '484 and '679 patents provide a method of treating various surface wounds with a topical biocidal formulation. The combination of teachings however is silent to the inclusion of the specific biocides recited in the claims. However the inclusion of the compounds into the formulation of the combination would be well within the level of skill in the art, as shown in the '151 patent.

13. The '151 patent discloses topical formulations comprising chelating agents such as EDTA and antibiotic agents such as neomycin, amikacin and tetracyclines (col.33, lin. 3-38; col. 34, lin. 25-48; col. 41, lin. 59-col. 43, lin. 54). The reference establishes the knowledge in the art of combining chelating agents and antibiotic/fungal agents in order to treat skin injuries topically. A skilled artisan would be motivated to include the antibiotics of the '151 patent in order to treat a wider range of bacterial infections.

14. With these things in mind, one of ordinary skill in the art would have been motivated to combine the compounds of the '151 patent into the combination of '679 and '484 in order to treat a wider range of bacterial infections. It would have been obvious to combine the teachings with en expected result of a topical wound healing formulation capable of treating a wider range of infections.

Response to Arguments

15. Applicant's arguments filed 5/16/06 have been fully considered but they are not persuasive. Applicant argues that:

a. The Raad reference does not disclose or teach surface treatment of infections since it discloses systemic fungal infections.

b. The Cuny reference does not discloses a synergistic combination between the chelating agent and the active antibacterial agent.

c. There is no motivation to combine the two reference

d. There is no motivation to combine the remaining references.

16. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

17. Regarding the Raad reference, it is the position of the Examiner that the reference provides sufficient disclosures to render the claims obviated in combination with the Cuny reference. Raad discloses an antimicrobial (fungal) formulation comprising a synergistic combination of a chelator and a drug. It is discovered that the chelator acts to reduce the growth of the microbes that cause fungal growth. This same chelator is used in the Cuny reference (EDTA), and given the level of skill in the art it would be obvious that the chelator would act similarly. The Raad reference discloses that though the infection is systemic, the treatment can be topical. The Cuny reference treats topical skin abrasions and lesions with a composition comprising EDTA and antibacterial agents. Following the disclosures of Raad, the skilled

artisan would be motivated to synergize the chelator and antibacterial concentrations in order to provide an improved formulation.

18. In response to applicant's argument that the Raad reference treats systemic infections, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

19. Applicant argues that since Raad discloses the treatment of systemic infection, it must teach away. Raad is relied upon for its disclosures of the importance of the synergy between the chelators and the biocide. Biocides can be interchanged within the level of skill in the art and would be obvious. The fields of endeavor are similar, namely inhibiting the growth of microbes, whether bacterial or fungal. It is the position of the Examiner that the topical treatment disclosed in Raad would treat and inhibit any infection at the site of application as well as the further systemic infection. The Cuny reference is relied upon for its disclosures of specific treatment techniques and situations such as burns, abrasions and cuts. It would be obvious to apply the method of synergistically combining chelators and biocides in order to provide a better formulation.

20. The motivation to combine the '516 Raad reference can be found in each reference since each combine biocides with EDTA. The '516 Raad reference merely establishes the level of skill in the art regarding the chelators EDTA and TRIEN, that they were equally available and interchangeable for those of ordinary skill in the art. The '516 Raad also provides a wider range of biocides in order to treat a wider range of infections.

21. The '151 reference finds its motivation in the Raad and Cuny reference since each combine biocides and EDTA. The '151 patent merely is used to establish the level of skill relating to specific antibiotics and chelators.

22. With these things in mind, it remains the position of the Examiner that the Raad and Cuny reference provide a method of treating infections. The Raad reference provides the teachings to synergize the biocide with the chelator and the Cuny reference provides the application sites and specific biocides. The further '516 Raad reference provides further specific biocides along with chelators that would be synergized by the method established in the Raad reference. The '151 patent again provide specific compounds following the suggestions of the Raad reference on the combination of chelators and biocides. For these reasons the claims remain obviated.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER